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Enforcement & Compliance Docket & Information Center

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United States Environmental Protection Agency
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Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue MW
Washington, DC 20460

RE: Establishment of Electronic Reporting; Electronic Records; Proposed Rule; August 31, 2001; 66 FR 46162

SCA Tissue North America LLC is opposed to the recordkeeping requirements and strongly urges EPA to withdraw these portions of the rule.

SCA Tissue North America LLC is a manufacturer of tissue, toweling, and napkins for the away-from-home market with operating facilities in Wisconsin, Arizona, Illinois, Georgia, Vermont, Indiana, and New York.

Paper companies are regulated under several EPA programs and must comply with recordkeeping requirements under these programs. The use of electronic, digital means to meet these recordkeeping requirements is common. As a result, compliance with the proposed recordkeeping provisions will be required at paper mills unless a paper-only system can be used (which is impractical in most situations). This is contrary to EPA's contention that the rule is voluntary.

The following comments summarize our major concerns with the proposed rule.

Definition of Electronic Record

The definition of "electronic record" would cover virtually all compliance information at a facility. Electronic record is defined to mean:

"any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."



Based on this definition, it appears that any piece of information that passes through a computer at any stage in its life cycle would be an electronic record. Little, if any, information would fail to meet this definition, and once the definition is met the recordkeeping criteria must be met. This definition is far too broad and must be significantly narrowed.

Electronic Recordkeeping System Requirements

The rule requires that an electronic recordkeeping system must meet very sophisticated information management criteria aimed at preventing fraud. EPA refers to these criteria as best practices for electronic records management. However, we are advised that these criteria represent the highest level of document security available. Companies that have examined this issue have stated that existing computer systems would not meet these requirements and that no commercially available, off-the-shelf software package meets the proposed criteria. Compliance with these requirements would likely involve significant upgrades to information management systems at nearly every facility regulated by EPA.

Cost

The cost for meeting the proposed recordkeeping system criteria could be staggering. The proposed rule is intended to be consistent with a FDA rule that took effect in 1997. A recent report indicated that many companies are still struggling to understand and implement the FDA rule and that many drug companies are spending in excess of \$100 million each to comply. One paper company estimates costs for complying with the proposed EPA rule in excess of \$1 million per facility. These costs far outweigh any benefits from the recordkeeping requirements.

Compliance

The rule states that an electronic record or electronic document will satisfy a recordkeeping requirement only if it is generated and maintained by a system that meets the specified criteria. In other words, failure to meet the technical system requirements constitutes failure to meet the underlying recordkeeping requirement (unless a paper-only system is used). This not only makes compliance with existing regulations much more costly (without any environmental benefit), it has the potential to cause "technical" compliance problems for companies that are unrelated to environmental performance.

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State Streamlining Efforts

Finally, the recordkeeping requirements will create a huge technical and financial barrier to streamlined electronic reporting initiatives being pursued by many states, including Wisconsin. These streamlining efforts are positive and EPA should make sure that any new requirements mesh with these state initiatives.

We strongly urge EPA to withdraw the recordkeeping portions of the rule. We do not object to the goal of improving data quality and security. However, any future effort to standardize recordkeeping requirements should focus more on streamlining and less on enforcement, and recognize that the vast majority of companies are committed to meeting both the letter and the spirit of the law.

Sincerely

Maurice Keesler

Vice President of Manufacturing and Technology

Maurico Keesler (goz)

SCA Tissue North America LLC